

## WHAT IS CLAIMED IS:

[Claim 1 has been deleted]

2. The <sup>method</sup> use of claim <sup>31</sup> 20 where said mammal is not immunized with an immunogen in such amounts and at such times as would  
5 substantially induce an immune-mediated disorder.

[Claims 3 & 4 have been deleted]

<sup>method</sup> 5. The use of claim <sup>31</sup> 20 wherein one immunogen other than a BCG, diphtheria, tetanus, pertussis, polio, hepatitis A, hepatitis B, hemophilus influenza, measles, mumps, <sup>or</sup> and rubella,  
10 influenza, cholera, BCG, plague, pneumococcus, neisseria, varicella, rabies, typhoid and yellow fever immunogen is <sup>provided</sup> administered.

<sup>method</sup> 6. The use of claim <sup>32</sup> 20, wherein for at least one such immunogen, the total dosage during the first 112 days after birth  
15 is substantially greater than that required for immunization against the infectious disease with which it is associated.

[Claim 7 has been deleted]

<sup>method</sup> 8. The use of claim <sup>31</sup> 20 wherein the first administration is preferably when the mammal is less than 28 days old, ~~more~~  
20 ~~preferably, less than 14 days old, and most preferably, about 7 days old.~~

<sup>method</sup> 9. The use of claim 21 wherein as a result of the subsequent administrations which the effect against the chronic immune-mediated disorder is enhanced, relative to that achieved  
25 by the first such administration.

<sup>method</sup> 10. The use of claim 21 wherein the shortest interval between two successive dosings of at least one immunogen is less  
than 28 days, ~~more preferably, less than 14 days, most~~  
~~preferably, about 7 days.~~

11. The use of claim 21 wherein, during the first 175 days from birth the longest interval between two successive dosings of at least one immunogen is less than 28 days, more preferably less than or about 14 days.

5 [Claims 12 & 13 have been deleted]

14. The <sup>method</sup> use of claim <sup>31</sup> 20 wherein the reduction in incidence of the disorder is at least 10%, more preferably at least about 20%, ~~most preferably at least about 50%.~~

15. A <sup>method</sup> use of claim <sup>31</sup> 20, wherein said chronic immune mediated disorder is a non-streptozotocin-induced diabetes mellitus, ~~or is SLE.~~

16. The <sup>method</sup> use of claim <sup>31</sup> 20, wherein said mammal is a human.

17. The <sup>method</sup> use of claim <sup>31</sup> 20, wherein at least one of said immunogens is an immunogen selected from the group consisting of  
 15 anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza,  
 20 parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens and a molecule that cross reacts to any of said  
 25 immunogens.

[Claim 18 has been deleted]

19. An immunogenic agent comprising a pediatric immunogen and a non-pediatric immunogen, wherein the non-pediatric immunogen is selected from the group consisting of anthrax,

AMENDED SHEET

plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens and a molecule that cross reacts immunologically to at least one of said immunogens.

20. Use of an immunogen in the manufacture of a composition to prophylactically or therapeutically reduce the incidence or severity of a chronic immune-mediated disorder in a mammal which, at the time of first administration of said immunogen, is less than 42 days of age.

21. The <sup>method</sup> use of claim <sup>31</sup> 20 wherein the mammal has already received at least one, preferably two, more preferably at least three, and most preferably at least four, dosings of said immunogen prior to administration of said composition.

22. Use of one or more immunogens in the manufacture of a kit to prophylactically or therapeutically reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, said kit comprising one or more receptacles each containing one or more immunogens, and instructions for administration of said immunogen(s) according to an immunization schedule, said schedule calling for a plurality of distinct dosings of a least one immunogen, the first dosing to occur when the mammal is less than 42 days of age.

[Claims 23 and 24 have been deleted]

25. A kit for use, prophylactically or therapeutically, to reduce the incidence or severity of a chronic immune mediated disorder, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, said kit further comprising labeling indicating that the kit can be used to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, and instructions for the prophylactic or therapeutic use of said immunogens to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal to which one or more doses of said immunogens are administered according to an immunization schedule set forth in said instructions, said immunogens, when so administered, acting to substantially reduce the incidence or severity of said chronic immune-mediated disorder, at least one of said immunogens also acting to substantially reduce the incidence or severity of an infectious disease to which said mammal is susceptible.

26. The kit of claim 25 wherein said instructions state that the kit is to be used to reduce the incidence or severity of diabetes.

27. A kit for use, prophylactically or therapeutically, to reduce the incidence or severity of a chronic immune mediated disorder, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, said kit further comprising labeling indicating that the kit can be used to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, and instructions for the prophylactic or therapeutic use of said immunogens to reduce the incidence or severity of a chronic

immune-mediated disorder in a mammal to which one or more doses of said immunogens are administered according to an immunization schedule set forth in said instructions, said immunogens, when so administered, acting to substantially reduce the incidence or severity of said chronic immune-mediated disorder, wherein said schedule, according to said instructions, calls for the first dose of an immunogen to be given before 42 days after birth.

28. The <sup>method kit</sup> use of claim 28 where if the disorder is diabetes, the diabetes was not streptozotocin-induced.

29. The <sup>method kit</sup> use of claim 29 wherein at least one immunogen other than a pertussis immunogen is administered.

30. The <sup>kit method</sup> use of claim 30 wherein said <sup>kit</sup> composition contains at least one immunogen selected from the group consisting of a diphtheria, tetanus, polio, Hepatitis B, Hemophilus influenza b, pertussis, and BCG immunogens.

add  
a<sub>1</sub>

add  
a<sub>2</sub>

add  
B<sub>1</sub>

add  
F<sub>5</sub>

add  
E<sub>1</sub>

add  
g<sub>13</sub>